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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,385	12/05/2003	Kevin Smith	SYN-8311	8814

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EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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09/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/728,385

Applicant(s)

SMITH ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 50-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-49 and 66-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-8, 10-15, 17-27, 66, 68, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitt (3,754,555). Schmitt discloses, at least in the figure and in col. 2, line 47 to col. 3, line 47; a retractor including a body (12 and 14); a retraction device for manipulating or grasping an object, where the device has a head (16 and 18), an actuator (22) movably disposed in the head; substantially first and second substantially rigid needles (24) independent of one another and each independently movably connected to the actuator and having an arcuate shape (just distal of 30); and an actuation device (32 or 34) connected to the proximal end of the body, where each needle is formed of a polymer (nylon) or steel (where the needles are rigid enough to retain its shape and not buckle or bend when penetrating tissue), and where the body includes a coil winding (12) and an outer jacket (14). Schmitt also discloses that the body has a longitudinal extent, where the head is connected removably or integrally formed (i.e., integrated) with the body; where the head defines openings (26), where the openings are disposed to permit movement of the needles therethrough without substantial deformation of the needles and substantially without friction (due to lubrication—see col. 3, lines 25-33), where the openings are disposed on

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opposing sides of the head and the needles are disposed on opposing sides of the actuator in substantial alignment with the openings, where the actuation device is connected removably to the proximal end of the body, where the actuator (32) is movably disposed in the body, where the arcuate shape of the portion is no greater than a circle and greater than a semi-circle, where the actuation device has a rod (34) integrally formed with the actuator, where the rod (32) is removably connected to the actuator, where the rod where the retractor includes proximal stop (e.g., 12)), where the actuation device has a locking device (e.g., 30) or an overstroke preventor, where the actuation device is a one-handed actuation device, where the head has cam surfaces (20) guiding the needles through the openings, where the actuation device selectively moves the actuator, and where the needles are sized to control penetration depth into tissues.

3. Claims 1, 2, 5-9, 16, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Hinchliffe (5,527,321). Hinchliffe discloses, at least in the figures 1-7A and in col. 4, line 15 to col. 5, line 58; a retractor including a body (16) with proximal and distal ends; a retraction device for manipulating or grasping an object, where the device has a head (28), an actuator (36) movably disposed in the head; substantially first and second substantially rigid needles (12 and 14) independent of one another and each independently movably connected or pivotally connected (via 44 and posts, 32 and 34) to the actuator and having an arcuate shape; and an actuation device (18) connected to the proximal end of the body or a one-handed action device (18) connected to the proximal end of the body, where the body has a longitudinal extent defining a

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longitudinal direction, the needles extend out of the head in a direction substantially orthogonal to the longitudinal direction. Hinchliffe also discloses that the head defines openings (at 30a and 30b) for respective ones of the needles, where the openings permit movement of the needles without substantial deformation and substantially without friction, where the openings are disposed on opposing sides of the head and the needles are disposed on opposing sides of the actuator in substantial alignment with the openings, and where surfaces of the openings guide the needles in direction substantially orthogonal to a movement direction of the actuator.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 29-48 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt (3,754,555) in view of Green (5,928,137). Schmitt discloses the invention

substantially as claimed. Schmitt discloses a tissue retractor including body and a retraction device as claimed. However, Schmitt does not disclose that the body and retraction device are sized to fit within a working channel of a flexible endoscope, nor does Schmitt disclose that the retractor is combined with a flexible endoscope having at least one working channel for receiving the body and the retraction device. Green teaches, at least in figure 5 and 8 and in col. 1, lines 9-28 and col. 6, lines 49-65; a flexible endoscope having at least one working channel (e.g., 152) for receiving a long-shafted endoscopic instrument, where the endoscope has application in various forms of endoscopy (including, e.g., thoracoscopy). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Green, to size the body and retraction device of Schmitt, so that the body and device can be accommodated by and combined with a flexible endoscope. A flexible endoscope with at least one working channel would not only allow access for Schmitt's device to a surgical site, it would also allow diagnosis and imaging of the site, especially where the site has narrow confines.

Response to Amendment

6. Applicant's arguments with respect to claims 1-14, 16, 18-28, 30-42, 44-49, and 66-69 have been considered but are moot in view of the new ground(s) of rejection.

Arguments with respect to claims 1, 15, 17, 29, and 43 have been considered, but are not persuasive. With respect to arguments regarding the rejection of claims 1, 15, and 17 under 35 U.S.C. 102 and based on the Schmitt reference: Schmitt indeed discloses, at actuation of the device, movement of one of the needles (24), i.e., distal

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portions thereof, that is "independent of and has absolutely no effect on the other," although ends of the needles are fixedly coupled to the piston (22). In other words, the needles are separate and distinct (i.e., independent) elements with portions movable in separate, diverging directions, where movement of one needle does not depend on movement of the other. Thus, the prongs (24) of Schmitt can be said to be "independent of one another and each independently movably connected to said actuator" as recited in claim 1.

With respect to arguments regarding the rejection of claims 29 and 43 under 35 U.S.C. 103 and based on Schmitt in view of Green: Green was not applied for any teachings on needles, but was applied for its teachings of a flexible endoscope including a working channel for receiving an "endosurgical instrument" with an "elongated shaft" and a distal "end-effector"—a description applicable to the instrument disclosed by Schmitt (which discloses the needles as claimed). Green's teachings regarding "graspers or scissors" are only exemplary of the combination of an endoscope and "long-shafted" instruments (e.g., "graspers or scissors").

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wittkamp (4,142,830) and Bradley et al. (5,374,275) teach devices usable as retractors.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

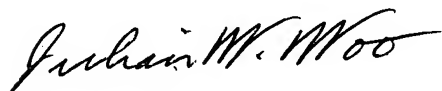
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Julian W. Woo". The signature is fluid and cursive, with the first name "Julian" and last name "Woo" clearly legible.

Julian W. Woo
Primary Examiner

September 8, 2007